which such treatment or prevention is desired in an amount sufficient to treat or prevent said pathology in said subject.

24. The method of claim 23, wherein said subject is a human.

29. A pharmaceutical composition comprising the polypeptide of claim 1 and a pharmaceutically acceptable carrier.

32. A kit comprising in one or more containers, the pharmaceutical composition of claim 29.

REMARKS

Upon entry of the present amendments, claims 1-4, 23, 24, 29, and 32 will be pending in the application. Claims 5-22, 25-28, 30, 31, 33-35, and 36-42 have been cancelled. No new matter has been added.

The claims are rejected for lack of enablement, lack of written description, and for being anticipated.

Rejections under 35 USC 112, first paragraph

Claims 1-4, 23, 24, 29, 32, 35, and 42 are rejected for lack of written description and enablement. Examiner alleges that while the polypeptide of the invention, SEQ ID NO:2 is approximately 91% homologous to human prothymosin α, SEQ ID NO:2 could not have any of the properties of this amino acid sequence. Applicants traverse.

Written Description

Claims 1-4, 23, 24, 29, 32, 35, and 42 have been rejected under 35 U.S.C. § 112, first paragraph for an alleged lack of adequate written description in the specification. This rejection is based on the recitation in claim 1 of 85% sequence homology to the sequence of SEQ ID NO:2. The Examiner maintains that there is not adequate written description for claims directed to nucleic acids sequences encoding polypeptides which are at least 85% similar to SEQ ID NO:2 in the specification.

Without conceding correctness of the Examiner's position, and in order to advance prosecution, Applicants have amended claim 1. Amended claim 1 no longer includes the claim language relating to 85% similarity. This amendment overcomes the written description rejection.

Enablement

It is the Examiner's position that the asserted specific utilities for the claimed invention are not considered to be substantial or credible utilities because the utilities are premised on the homology of the disclosed full-length protein (SEQ ID NO:2) to the prothymosin α family of immunomodulatory molecules. According to the Examiner, Applicants suggest that SEQ ID NO:2 may be a novel member of the prothymosin α family. The Examiner further states that "Absent factual evidence, a percentage sequence similarity less that 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of a known biomolecule with a similar sequence." (Office Action at page 5). Therefore, according to the Examiner, because the claimed invention is not supported by other specific teachings about the protein the specification fails to meet the requirements of enablement.

Claims 1-4, 23, 24, 29, 32, 35, and 42 are directed to a polypeptide comprising the amino acid sequence of SEQ ID NO:2, and compositions, methods, and kits containing such amino acid

molecules. The specification discloses that SEQ ID NO:2 is a novel member of the prothymosin α family and asserts a utility based, in part, on homology between SEQ ID NO:2 and known prothymosin α family members, including, but not limited to, human prothymosin α (*See* specification page 12, line 26, to page 13 line 4). The Utility Examination Guidelines state that "when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion." (Fed. Reg., Vol. 66. No. 4, January 5, 2001, p. 1096). If the Examiner has sufficient evidence to rebut such an assertion, and rejects the claims for lack of utility, then the burden shifts back to the Applicant to provide evidence supporting such a well-established utility.

In this case, SEQ ID NO:2 is highly homologous to many members of the prothymosin gene family. (*See* Exhibit A, attached hereto). Thus, the existence of this homology to the family demonstrates that SEQ ID NO:2 is a novel member of the prothymosin α family. Accordingly, one skilled in the art would recognize that the disclosed sequence of the polypeptide of the present invention, can be expected to function as a member of the prothymosin α family, to act as an immunomodulatory molecule. Therefore, Applicants assert that the polypeptide of SEQ ID NO: 2, as a novel member of this family, has a specific, substantial, and credible utility.

The Utility Examination Guidelines further state that "when a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein." (Fed. Reg., Vol. 66. No. 4, January 5, 2001, p. 1096). Prothymosin α protein family members share a specific, substantial, and credible utility and are sufficiently conserved, thereby imputing the same utility to a novel member of their protein class, such as SEQ ID NO:2.

Claims 35 and 42 have been cancelled, so this rejection is moot insofar as it applies to these claims.

Rejections under 35 USC 112 second paragraph

Claim 35 was rejected under 35 USC 112 second paragraph for not distinctly claiming the invention. Claim 35 has been cancelled so this rejection is now moot.

Rejections under 35 USC 101

Claim 35 was rejected under 35 USC 101 for the recitation of a use not setting forth any steps involved in the process. Claim 35 has been cancelled so this rejection is now moot.

Rejections under 35 USC 102(b)

Claims 1, 4, 23-24, 29, 32, and 35 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 4,659,694 ("Horecker"). The rat and human prothymosin are > 85% homologous to SEQ ID NO:2. Claim 1 has been amended to claim only polypeptides comprising SEQ ID NO:2. There are no sequences in Horecker that read on claim 1 as amended. Claims 4, 23, 24, 29, 32 and 35 ultimately depend from claim 1, so if Horecker does not read on claim 1 it does not read on its dependent claims.

On the basis of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A petition for extension of time and accompanies this response. The Commissioner is authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 15966-572.

Respectfully submitted,

Sean M. Coughlin, Reg. No. 48,593

December 17, 2002

Ivor R. Elrifi, Reg. No. 39,529
Attorney for Applicant
c/o MINTZ, LEVIN
One Financial Center
Boston, MA 02111
Tel: (617) 542 6000
Fax: (617) 542 2241

Version Marked to Show Changes

Amend claims 1 and 2 as follows:

An isolated polypeptide comprising an amino acid sequence of SEQ ID NO:2 [selected from the group consisting of:

a) a mature form of the amino acid sequence given by SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20;

b) a variant of a mature form of the amino acid sequence given by SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20, wherein any amino acid in the mature form is changed to a different amino acid, provided that no more than 15% of the amino acid residues in the sequence of the mature form are so changed;

c) the amino acid sequence given by SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20;

d) a variant of the amino acid sequence given by SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20 wherein any amino acid specified in the chosen sequence is changed to a different amino acid, provided that no more than 15% of the amino acid residues in the sequence are so changed; and

e) a fragment of any of a) through d)].

2. The polypeptide of claim 1 that is a naturally occurring allelic variant of the sequence given by SEQ ID NO: 2[, 4, 6, 8, 10, 12, 14, 16, 18, and 20].

TRA 1744520v1